Optimal Size AMBU® Laryngeal Mask Airway Among Asian Adult Population

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SUMMARY

Aim: This was a randomized single blinded study to determine optimal size for Ambu®LMA (ALMA) among Malaysian adult population.

Methods: One hundred and twenty six non-paralyzed anaesthetized adult patients were block randomized into size 3, 4 and 5 Ambu®LMA. Optimal size is defined primarily by oropharyngeal pressure (OLP). Pharyngeal injury and ease of insertion are also taken into consideration.

Results: Mean OLP was significantly higher for Size 4 and 5 compared to size 3 (p<0.001) but similar between size 4 and 5. Number of insertion attempts and insertion time were similar between sizes. Size 5 required more manipulations during insertion (p<0.005) and had higher pharyngeal injury (p=0.001) compared to size 3 and 4.

Discussion: We recommend size 4 ALMA as the optimal size for Malaysian adults in view of the higher OLP compared to size 3, yet less pharyngeal injury than size 5 in spontaneously breathing patients.

KEY WORDS:
Laryngeal mask airway, Size Selection, Malaysian Adult

INTRODUCTION

Laryngeal mask airway (LMA) has gained widespread popularity among anaesthetists as a routine airway management device during general anaesthesia and as a device for rescue airway management [1]. Compared to tracheal intubation, LMA is better tolerated, causes less haemodynamic instability during induction and emergence, causes less coughing, sore throat and does not require neuromuscular monitoring. At the same time, it allows 'hands-free' anaesthesia[2] and less operation room pollution compared to face mask ventilation [3,4]. However, appropriate LMA size is one of the keys to ensure its optimal use [5]. Optimal size LMA should have adequate oropharyngeal leak pressure (OLP), easy to insert and minimal trauma.

AMBU® AuraOnceTM Laryngeal Mask (ALMA) is a latex free supraglottic device which has cuff, mask and airway tube molded in a single unit to minimise separation. It features a special curve that mimics natural human anatomy at the airway tube to ensure easy, atraumatic tube insertion and removal. Studies have demonstrated that ALMA is as safe and effective as other supraglottic airway device [6]. The importance of choosing the optimal size of ALMA for patients cannot be overemphasize. Inappropriately smaller LMA may cause obstruction and inadequate airway whereas inappropriately larger ALMA may cause difficult and traumatic insertion. All these unwanted morbidities may be prevented if we could choose the optimal size ALMA for our patients. Until now, the choice of ALMA size is based on body weight as recommended by the manufacturer, i.e. Size 3 for patient weighing 30-50kg, size 4 for 50-70kg and size 5 for >70kg. For other types of LMA, it was recognized that LMA size selection based on patient's weight alone has its limitations.7 There are many who continues to use size 3 for women and size 4 for men. Therefore, this study aims to determine optimal size for ALMA in Malaysian adult population and factors that affect size selection.

MATERIALS AND METHODS

This is a prospective randomized study. After approval from research ethics committee of the University of Malaya Medical Centre (UMMC) and written informed consent, 126 patients were recruited for this study. Inclusion criteria were patient classified as ASA I-II, aged 18-65 years old, body mass index (BMI) of 18-30 kg/m^2, presented to UMMC for surgery where general anaesthesia was indicated. Exclusion criteria were patient with known or anticipated airway difficulty, inadequate cervical mobility or malformation, reduced mouth opening <2.5cm, recent upper airway infection, fasting time less than 6 hours and at increased risk of aspiration. Patients for head and neck surgery and laparoscopic abdominal surgery were also excluded.

These patients are block randomized into 3 groups i.e. Group 1, 2 and 3 for size 3, size 4 and size 5 ALMA respectively. Each block has fifteen sealed envelopes, each with a sheet of paper labeling group number. There are 5 of each group in one block. Once a patient is recruited, the patient is randomized according to the group labeled in the envelope which is randomly picked by an independent observer. After fifteen patients were recruited and completion of one block, the next block with another fifteen envelopes are used for the next fifteen patients. The last block only has 6 envelopes with 2 of each group.

Demographic data included age (year), gender, race, height (cm), weight (kg), BMI, Mallampati score, maximum inter-incisor distance (cm), thyromental distance (cm) and sternomental distance (cm) were documented.

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The ventilator DATEX AESTIVA 7100 (Datex Ohmeda Aestiva; GE Healthcare, Cheshire, USA) and anaesthetic circuit were tested for leaks before each use. All patients had established intravenous access and standard monitoring (pulse oximeter, non-invasive blood pressure monitor, electrocardiograph, capnograph, oxygen and volatile agent analyzers) before induction of anaesthesia. The ALMA is lubricated with water-based lubricant. Size of ALMA used depended on which group the patient was being randomized into earlier. Patient's head was supported on firm silicon head ring and kept at neutral position. After preoxygenation with 100% O2 for 1 minute, patient was induced with 1mcg/kg fentanyl followed by 2mg/kg propofol approximately 2 minutes later. During this interval, patient was also co-induced with 2% sevoflurane in 100% O2 at flow rate of 8L/min. Adequate depth of anaesthesia is defined by disappearance of eye lash reflex and complete jaw relaxation. Once adequate anaesthesia was achieved, ALMA was inserted using digital technique and cuff inflated to intracuff pressure of 60cmH2O using handheld pressure gauge device (VBM, Medizintechnik, Sulz city, Germany).

All insertions were done by single investigator who has used classic LMA >200 times and ALMA >20 times. Ease of insertion was defined by insertion time, number of insertion attempts and whether jaw thrust and/ or chin lift manoeuvres were required to aid insertion. Insertion time was defined as the time when tip of ALMA placed at upper incisor to the time when square wave end-tidal carbon dioxide ($ETCO_2$) tracing or expiratory tidal volume (VT_E) ≥5ml/kg was reached with manual assisted ventilation. Insertion time (seconds) was recorded by a blinded observer with calibrated stopwatch. Airway inadequacy was defined as VT_E <5ml/kg, ETCO2>50mmHg and SpO2<95%. If any of these were to occur, attempt was made to improve the airway by repositioning manoeuvres (jaw thrust, chin lift) and if necessary reinsertion of ALMA. If all these manoeuvres failed, assisted ventilation was done manually with face mask and tracheal intubation to maintain airway and ventilation. One failed attempt was defined as removal of ALMA from the mouth. Failure to insert was defined as when 2 failed attempts occurred. During insertion, any adverse events (i.e. coughing, gagging, hiccup, airway obstruction, vomiting, regurgitation, aspiration, laryngospasm and bronchospasm, trauma on lips and dentition) were documented. During oropharyngeal leak pressure (OLP) measurement, the adjustable pressure limiting (APL) valve was closed completely and fresh gas at flow of 3L/min. OLP was noted as the pressure indicated at ventilator pressure gauge when audible leak was heard via auscultation over the mouth and a fall in the pressure tracing. The anatomical placement of ALMA was assessed via fibreoptic bronchoscopy and graded as proposed by Brimacombe and Berry[8] (i.e. Grade 4: only vocal cords seen; Grade 3: vocal cords and posterior epiglottis seen; Grade 2: vocal cords and anterior epiglottis seen; Grade 1: vocal cords not seen).

Anaesthesia was maintained with 35% oxygen, nitrous oxide and sevoflurane to achieve minimum alveolar concentration (MAC) of 1-1.3. Patients breathed spontaneously throughout the procedure. At the end of surgery, anaesthesia was discontinued and the ALMA was removed when patient was awake and protective airway reflex returned. Indicators for oropharyngeal injury includes evidence of blood stain on removed ALMA and patients' complain of sore throat during swallowing half an hour after ALMA removal.

Optimal size ALMA was defined as ALMA achieving OLP≥20cmH_2O. This was based on earlier literature which showed that there was no incidence of gastric insufflation in spontaneously breathing patients with OLP≥20cmH_2O [9]. Optimal size ALMA should also have minimal oropharyngeal injury and easy insertion.

Sample size calculation was based on published study on ALMA, quoting mean OLP of 24cmH_2O and standard deviation of 5.5cmH_2O [6]. With type I error set at 0.05, a sample size of 38 in each group was needed to have 80% power to detect a difference in mean OLP of 5cmH_2O based on Altman's normogram [10]. The sample size was expanded to 126 to account for drop out rate and missing data of 10%. All results were stated in mean ± SD unless otherwise stated. For statistical analysis, SPSS 16.0 is used. Parametric data is tested with ANOVA test and post hoc Bonferroni test. The primary outcome endpoint OLP is tested with ANCOVA with adjustment of covariates. Non-parametric data is tested with chi-square test. P value <0.05 is taken as statistical significant.

RESULTS

Of all 126 patients recruited, one patient with BMI of 30.1 and randomised to size 5 ALMA was wrongly recruited due to calculation error of BMI at recruitment. Therefore, his data was excluded from the analysis. Of the other 125 patients, 42 patients were randomised to size 3 and size 4 groups each respectively and 41 patients to size 5 group. The demography of these 125 patients is shown in Table I. There appeared to be no significant difference among patients of these 3 groups in terms of age, height, weight, BMI, maximum inter-incisor distance and thyromental distance tested with ANOVA ($p > 0.05$). Similarly, there were no difference among patients of these 3 groups in terms of gender and Mallampati score tested with Chi-square test ($p>0.05$).

The results were summarized in Table II, III and IV. Among 42 patients in size 3 group, there was one failed insertion due to obstruction which could not be remedied by jaw thrust and chin lift in both first and second attempts. In size 4 group, all 42 patients have successful insertion, 41 at first attempt and one at second attempt. In size 5 group, only 34 patients have successful insertion at first attempt and three patients in second attempt. Four patients in size 5 group suffered from failed insertion and all of them due to failure to manipulate the cuff through the mouth or resistance met at the back of mouth despite aid of jaw thrust. Demography of patients with failed insertion is summarized in table IV. Mean insertion time for size 3, 4 and 5 group were 32.03±15.67s, 33.21±12.82s and 38.56±16.48s respectively and there was no statistical difference ($p=0.127$). Significantly more patients in size 5 group required jaw thrust manoeuvre compared to size 3 and 4 ($p=0.008$).

The mean OLP for size 4 and size 5 groups were 24.0±4.5cmH_2O and 24.6±6.5cmH_2O respectively. These were significantly higher than size 3 with mean OLP of

Table I: Demographic data and anatomical parameters

	Size 3	Size 4	Size 5
Male/female, n	9/33	13/29	12/29
Age in year, mean (range)	39 (20-60)	40 (18-65)	39 (18-61)
Height in cm, mean (range)	160 (149-175)	161 (148-175)	160 (142-184)
Weight in kg, mean (range)	59.4 (38.2-85.0)	58.8 (39.0-82.0)	58.4 (39.0-80.0)
BMI in kg/m2 (mean, range)	23.0 (15.3-30.0)	22.8 (16.2-30.0)	22.9 (15.6-30.0)
Mallampati score, 1/2/3	27/9/6	28/8/6	29/10/3
Maximum inter-incisor distance in cm, mean (range)	4.0 (3.0-5.5)	4.0 (3.0-5.5)	3.9 (3.0-5.0)
Tyromental distance in cm, mean (range)	7.1, (4.0-10.0)	7.4 (5.0-9.5)	7.2 (5.0-9.0)
Sternomental distance in cm, mean (range)	15.4 (11.5-18.5)	16.6 (13.5-20.5)	16.0 (11.0-21.0)

Table II: Comparison of oropharyngeal leak pressure (OLP), ease of insertion, fibreoptic assessment and complications

	Size 3	Size 4	Size 5
Oropharyngeal Leak Pressure, OLP			
Mean (95% CI)[a,b]	19.8 (18.9, 21.26)	24.0 (22.6, 25.4)	24.6 (22.5,26.8)
OLP≥20 cmH2O (n)	22	34	30
Ease of insertion			
Insertion attempts; 1/ 2/ fail	41/0/1	41/1/0	34/3/4
Insertion times in seconds[c] (mean, range)	32.03, 17.26-93.98	33.21, 14.90-71.11	38.56, 18.00-80.09)
Jaw thrust manoeuvre used;d Yes/No	5/36	6/36	14/23
Chin lift manoeuvre used; Yes/ No	3/38	1/41	2/35
Fibreoptic assessment			
Grade 4 (Vocal cords only)	21	27	23
Grade 3 (Vocal cords and posterior epiglottis)	9	7	5
Grade 2 (Vocal cords and anterior epiglottis)	11	6	8
Grade 1 (No vocal cords)	0	2	1
Grade 0 (Failed to insert)	1	0	4
Complications			
Blood on device; Yes/ No	1/40	3/39	12/25
Sore throat; Yes/No	1/40	1/41	4/33

[a]With ANOVA, the mean difference between groups is significant at p<0.001 level.
[b]Post hoc test with Bonferroni test showed the mean difference between size 3 and size 4, size 5 are significant at p<0.05
[c]ANOVA test
[d]Pearson Chi-Square test, P<0.05

Table III: Comparison of OLP between sizes controlled for potential confounders

Size	n	Adjusted meana (95% CI)	Adj. mean diff. (95% CI)b	F stat. (df)	P value
Size 3	41	19.0 (17.0, 21.1)	Between size 3 and size 4 4.2 (1.3, 7.2), p=0.002;	8.462 (2, 105)	P<0.001
Size 4	42	23.3 (21.1, 25.5)	Between size 3 and size 5 4.5 (1.6, 7.5), p=0.001;		
Size 5	38	23.6 (21.5, 25.6)	Between size 4 and size 5 0.3 (-2.5, 3.1), p=1.0		

[a]Adjusted mean using ANCOVA controlled for age, height, weight, mouth-opening, tyromental distance and sternomental distance, race, gender and Mallampati
[b]Bonferroni adjustment for 95% confidence interval for difference

Table IV: Demographic data of patients with failed ALMA insertion

Pat.	ALMA size	Gender	Race	Age (year)	Height (cm)	Weight (kg)	BMI (kg/m²)	Mal. score	IID (cm)	TMD (cm)	SMD (cm)
1	3	Male	Indian	22	173	52.0	17.4	2	3.5	4.0	13.5
2	5	Female	Malay	45	142	42.4	20.8	1	4.0	6.0	17.0
3	5	Female	Malay	49	156	53.0	21.8	2	3.5	6.0	12.0
4	5	Female	Malay	36	157	54.0	21.9	1	4.0	8.0	18.0
5	5	Female	Malay	19	158	39.0	15.6	1	3.5	6.5	15.5

Mal. score, Mallampati score; IID, inter-incisor distance; TMD, thyromental distance; SMD, sternomental distance

19.8±4.5cmH_2O, p<0.001. After adjusted for age, race, gender, height, weight, Mallampati, maximum inter-incisor distance, tyromental distance and sternomental distance, the adjusted mean OLP for size 4 and 5 groups were 23.3±1.1cmH_2O and 23.6±1.1cmH_2O respectively. These were still significantly higher than size 3 with adjusted mean OLP of 19.0±1.0cmH_2O at p<0.001. The adjusted mean difference between size 3 and size 4 groups were 4.2cmH_2O (95% CI 1.3, 7.2), p=0.002. The adjusted mean difference between size 3 and size 5 groups were 4.5cmH_2O (95% CI 1.6, 7.5), p=0.0014. The adjusted mean difference between size 4 and size 5 groups were 0.3cmH_2O (95% CI -2.5, 3.1), p=1.0. There were 34 patients in size 4 group and 29 patients in size 5 group who obtained OLP greater than 20cmH2O compared to 22 patients in size 3 group. This is also significant at p=0.011.

Evidence of blood on device was significantly higher in size 5 group compared to size 3 and 4 groups (p<0.001). They were one in size 3 group, three in size 4 group and 12 in size 5 group respectively. Incidence of sore throat between the three groups was similar, one each in both size 3 and 4 groups and four in size 5 group.

As for the fibreoptic bronchoscopic grade, the distribution of each grade between the three groups were similar with no significant difference (p=0.223). Majority of patients had grade 4 view. There were 21 in size 3 group, 27 in size 4 group and 23 in size 5 group respectively. There were two patients in size 4 group and one in size 5 group with grade 1 view. Despite having less than ideal bronchoscopic view, these patients achieved adequate ventilation and therefore the ALMA was not removed.

From this study, there did not appear to have any relation between OLP and any patient factors (ie. Age, gender, height, weight and anatomical parameters).

DISCUSSION

Our study showed that mean OLP achieved by patients in size 4 group (23.3±1.1cmH_2O) and size 5 group (23.6±1.1cmH_2O) were significantly higher than size 3 group (19.0±1.0cmH_2O) at p=0.001 when possible confounding factors of age, height, weight, mouth-opening, tyromental distance and sternomental distance, race, gender and Mallampati score were controlled. There were also significantly more patients with size 4 and size 5 groups achieved OLP≥20cmH2O compared to patients with size 3 group, p=0.011.

High OLP is critical as air leak predisposes patient to inadequate ventilation. Air leak also predisposed patients to gastric insufflation and therefore increased risk of regurgitation. In spontaneously breathing patients, Keller et al noted that there was no incidence of gastric insufflation with peak airway pressure <20cmH_2O [9]. With controlled ventilation, Weiler *et al* in their study noted that in 27% of their patients, gastric air insufflation occurred at inspiratory pressure between 19-33cmH_2O [11]. Therefore in principle, the lower seal of the size 3 ALMA may make it less suitable than the size 4 and size 5 especially in controlled ventilation. Other disadvantages of air leak are operation theatre pollution[11, 12] and greenhouse effect.

We also noted significantly higher incidence of blood on device in size 5 group, p<0.001, compare to size 3 and 4 groups. This suggests trauma during insertion and manipulation of ALMA through oropharyngeal space and may indicate poor fit. Surprisingly, blood on device occurred even in patients with successful insertion with one attempt and no manipulation required. Nonetheless, the incidence of sore throat post ALMA removal did not differ significantly between groups, p=0.14, ranging from 2-12%, which is comparable to earlier studies [13,14].

Mean insertion time for all 3 sizes were similar between groups. However, there were more patients with failed insertions in size 5 group. All of them female with their weight ranged between 39.0-54.0 kg. Failed insertions were due to inability to manipulate the cuff in the mouth despite jaw thrusts. In size 5 group too it was noted that significantly more patients required jaw thrust maneuver to aid insertion compared to the other two groups. These findings may suggest size 5 ALMA is not as easy to insert compared to size 3 and 4. Thus it is possible that in rescue airway management, one is more likely to have difficult or failed insertion with size 5 ALMA in adult Malaysian population, making it less than ideal size in emergency situation.

Our study also noted that all patients achieved adequate ventilation regardless of the grade of fibreoptic bronchoscopic assessment. The distribution of each grade between the three groups were similar with no significant difference (p=0.223). This is in agreement with earlier study that fibreoptic views do not provide measure of functional seal [15].

Optimal size ALMA should have adequate OLP to allow adequate ventilation without gastric insufflation which may increase risk of aspiration. At the same time, morbidity such as oropharyngeal injury should be minimal. It should also be easy to use with high success rate of insertion. Therefore we recommend size 4 ALMA as the optimal size ALMA for normal Malaysian adult population in view of the higher OLP compared to size 3 and less oropharyngeal morbidity, easier to insert compared to size 5.

From our study of 125 patients, neither patient's height, gender, weight parameters (i.e. exact body weight, body mass index and ideal body weight) nor patient's upper airway geometry (i.e. Mallampati score, thyromental distance and sternomental distance) seemed to affect OLP achieved. Similar findings have also been highlighted in previous studies with other LMAs. Berry et al showed that there was no correlation between weight, gender or any other easily measured anatomical variable and optimal LMA size [7,16]. However, as or study is not aiming at predicting ALMA size selection based on these factors, it is not powered with enough sample to conclusively deny correlation between OLP, optimal ALMA size and patients' parameters. Further study need to be conducted for this purpose.

More than two third of our sample population are females. This reflects the workload and patient population where general anesthesia with laryngeal mask is used in our centre. However, this does not influenced the results as patients are block randomized and statistical analysis showed no

differences between groups. We also noted that the insertion times were longer comparable to earlier studies[17,18], this could be due to study methods where patients were not paralysed for laryngeal mask airway insertion.

CONCLUSION

In conclusion, we recommend size 4 ALMA as the optimal size ALMA for normal Malaysian adult population in view of the higher OLP compared to size 3 and less oropharyngeal injury, easier insertion compared to size 5.

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